

REMARKS

This application has been carefully reviewed in light of the Office Action of May 9, 2005, wherein:

A. Claim 1 was rejected under 35 U.S.C. 112, first paragraph.

Turning now to the Office Action, the Examiner maintained her previous rejection, rejecting Claim 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner stated that the above rejection was maintained because what is disclosed in the specification does not accurately describe what has been deposited in the Agricultural Research Service Patent Culture Collection (NRRL). The specification and claim recite a pure culture of *Bacillus odysseyi* strain 34hs-1T under accession number of NRRL B-30641T. However, the NRRL depository recites *Bacillus odysseyi* strain 34hs-1 having an accession number of NRRL B-30641. The Examiner stated that the specification and the claims must reflect what has actually been deposited. The Examiner further stated that the deposit for patent purposes must correspond to the material particularly claimed and disclosed in the specification as filed. See 37 CFR 1.804(a). Additionally, the Examiner stated that the requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C 112 and provides an antecedent basis for the biological material which either has been or will be deposited before the patent is granted.

The Examiner stated that what was disclosed in the specification does not accurately reflect what was deposited. This is not true. The superscript T as applied to *Bacillus odysseyi* (i.e., 34hs-1^T) denotes that the strain has been given the status type-strain. One strain of a species is designated as the type-strain, meaning that it is usually one of the first strains studied. With regards to the present invention, it is meaningless in this context and is the same with or without the superscript T. Therefore, what was deposited is accurately reflected by the specification and claim. However, to overcome this rejection and remove any ambiguity, the

Applicant proposes to amend the specification and the claim to remove any reference to the type-strain (i.e., superscript T). Thus, the specification and claim now clearly reflect what has been deposited with the depository.

The Applicants believe that with the above amendments, the application is now in allowable condition. Thus, the Applicants respectfully request that the Examiner withdraw the rejection of Claim 1.

B. Claim 1 was rejected under 35 U.S.C. §102(b)

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Venkateswaran, K. et al. (*Bacillus nealsonii* sp. nov., isolated from a spacecraft-assembly facility, whose spores are γ -radiation resistant, International Journal of Systematic and Evolutionary Microbiology, July 2002; 53: 165-172).

Claim 1 is drawn to an isolated biologically pure culture of *Bacillus odysseyi* strain 34hs-1T under accession number NRRL B-306417. The Examiner stated that Venkateswaran et al. discloses spore-formers isolated from a spacecraft being that of the genus *Bacillus*. The Examiner further stated that Venkateswaran et al. discloses that spores of the bacterial species exhibited resistance to UV, γ -radiation, (H₂O₂) and desiccation. The Examiner also stated that the instant specification characterizes the *Bacillus odysseyi* sp. nov., as round spores that are resistant to Ultra Violet (UV) and gamma radiation, Hydrogen Peroxide (H₂O₂) and desiccation (page 5, section 00035). The Examiner further stated that aside from the difference in the names of the above strains it is unclear what the differences are between the *Bacillus nealsonii* sp. nov strain, which was isolated from a spacecraft assembly facility and the *Bacillus odysseyi* strain, which was isolated from a spacecraft assembly facility. The Examiner concluded that the organisms appear to be the same microorganisms by a different name.

The cited reference discloses *Bacillus nealsonii*, not *Bacillus odysseyi*. The 102(b) rejection is an improper rejection as the *Bacillus odysseyi* and *Bacillus nealsonii* are two very different species of *Bacillus* with different characteristics. Following are descriptions of the two species, highlighting several distinct differences between the two species.

Description of *Bacillus nealsonii* FO-92T:

Strain FO-92T is a Gram-positive, facultatively anaerobic, rod-shaped, spore-forming bacterium. The cells are 4–5 mm in length, 1 mm in diameter and are motile. On TSA medium incubated at 32 °C, young colonies are beige, irregular, with a diameter of 3–4 mm, rough, umbonate with undulate or lobate edges. Endospores of strain FO-92T are oval, with one spore per cell. Purified spores contain a distinctive extraneous layer. Cross-sections of the spores clearly show a loosely arranged layer outside the spore coat. The strain FO-92T produced catalase but hydrogen sulfide was not produced from thiosulfite. *Bacillus* species that produce acid from a variety of sugars, including glucose, are classified under rRNA group 1. Spores of these species were ellipsoidal and did not swell the mother cell. These species are considered the ‘subtilis group’ because of their similar physiological properties. Strain FO-92T, isolated from the Spacecraft Assembly Facility at NASA Jet Propulsion Laboratory (JPL-SAF), exhibited the characteristics necessary to place it into the rRNA group 1.

Description of *Bacillus odyseyi* 34hs-1

Strain 34hs-1 is a Gram-positive, aerobic, rod-shaped, spore-forming bacterium. The cells are 4–5 mm long, 1 mm in diameter and motile. On TSA medium incubated at 32 °C, young colonies are beige, round, ~3 mm in diameter, fairly smooth and flat with entire edges. Endospores of strain 34hs-1 (1 mm in diameter) are terminal, round, with one spore per cell and swell the mother cell. Ultrathin sections of spores of strain 34hs-1 showed the presence of an exosporium, spore coat, cortex and core. Strain 34hs-1 grew between 25 and 42 °C, with optimum growth at 30–35 °C, and over the pH range 6–10 (optimum 6–7). It did not require Na⁺ for growth. This strain produced catalase, but not cytochrome oxidase, gelatinase, urease, tryptophan deaminase, lysine or ornithine decarboxylase or arginine dihydrolase. It did not show denitrification or acetoin production. Strain 34hs-1 did not ferment glucose nor utilize glucose as a sole carbon source. After prolonged incubation (>3 days), arabinose was assimilated; however, this is not a discriminatory phenotypic trait. Hydrogen sulfide was not produced from thiosulfite. Most roundspored *Bacillus* species, including strain 34hs-1, are not able to grow in the absence of oxygen. Strain 34hs-1, isolated from JPL-SAF, exhibited the characteristics necessary to place it into the rRNA group 2.

As described above, *Bacillus nealsonii* is an entirely different species than *Bacillus odysseyi*. Because the cited reference does not disclose *Bacillus odysseyi*, the Applicants respectfully request that this rejection be withdrawn.

C. Claim 1 was rejected under 35 U.S.C. §102(a)

Claim 1 was rejected under 35 U.S.C. 102(a) as being anticipated by La Duc, M. et al. (Characterization of microbes intimately-associated with the Mars Odyssey Orbiter and its assembly facility, Abstracts of the general meeting of the American Society for Microbiology, 2002; 102: 389).

The Examiner stated that Claim 1 is drawn to an isolated biologically pure culture of *Bacillus odysseyi* strain 34hs-1T under accession number NRRL B-30641T. The Examiner further stated that the instant specification describes *Bacillus odysseyi* sp. nov., as round spores that are resistant to Ultra Violet (UV) and gamma radiation, Hydrogen Peroxide (H₂O₂) and desiccation (page 5, section 00035). The Examiner stated that La Duc et al. disclosed the technical description and admission in the priority document 60/440,790, faxed page 1 and 2 of the above strain at an annual conference. The Examiner further stated that LaDuc cited that several spore-forming isolates were found to possess a plethora of resistances, some of which included resistance to g-radiation, UV, H₂O₂, and desiccation (abstract). The Examiner also stated that the strain of the instant application and the strain of the cited prior art have the same properties. The Examiner concluded that since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

The cited reference was a conference held on May 19-23, 2002. The material presented in the reference covered multiple subjects and was co-authored by four individuals. Two of the authors, La Duc M.T., and Venkateswaran K.J., are the inventors of the present invention. As sworn to in the attached declaration, the present invention was invented at least as early as May

Application No.: 10/759,327
Amendment Dated: September 09, 2005
Reply to Office Action of May 9, 2005

19, 2002 and was diligently pursued with the purpose of its reduction to practice or until the priority filing date of January 17, 2003 (Attached hereto as appendix A is a declaration under 37 CFR 1.131).

Because the present invention was invented at least as early as May 19, 2002, the Applicants respectfully request that the Examiner withdraw this rejection and provide for timely allowance of Claim 1.

Application No.: 10/759,327
Amendment Dated: September 09, 2005
Reply to Office Action of May 9, 2005

5 **Concluding Remarks:**

The Applicants respectfully submit that in light of the above comments and remarks, the Claim is now in allowable condition. The Applicants thus respectfully request timely allowance of the pending Claim.

- 10 In the event the Examiner wishes to discuss any aspect of this response, or believes that a conversation with either Applicants or Applicants' representative would be beneficial the Examiner is encouraged to contact the undersigned at the telephone number indicated below.
- 15 The Commissioner is authorized to charge any additional fees which may be required or credit overpayment to deposit account no. 50-2691. In particular, if this response is not timely filed, the Commissioner is authorized to treat this response as including a petition to extend the time period pursuant to 37 CFR 1.136(a) requesting an extension of time of the number of months necessary to make this response timely filed. The petition fee due
- 20 in connection therewith may be charged to deposit account no. 50-2691.

Respectfully submitted,



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